

REMARKS

This paper is in response to the Official Action mailed October 9, 2008. In the present paper, claims 1, 11, 24-26 and 34 are amended, claims 36 and 37 are added and claims 12-14, 17-19 and 21-23 are canceled. Claims 4, 5, 8, 15, 16, 20, 28, 29 and 32 were canceled in a previous paper. Claims 1-3, 6, 7, 9-11, 24-27, 30, 31 and 33-37 are now presented for the Examiner's consideration in view of the following remarks.

The Present Invention

The inventors have discovered a system and method for identifying and communicating with potential clinical trial participants. The invention permits the use of a large transactional database containing transactions between health care providers and payers, for identifying clinical trial candidates without compromising privacy. Such a database contains highly reliable data. The exchange of data is structured so that only a trusted candidate contact such as a candidate's physician has simultaneous access to both (1) the identity of a patient and (2) information about a clinical trial in which the patient is proposed to participate.

In the Official Action, the Examiner has rejected claims 1, 3, 6, 10-14, 17-19, 21, 23-27, 30 and 33-35 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Publication No. 2002/0099570 to Knight ("Knight") in view of U.S. Patent Publication No. 2003/0046562 to Uchikubo et al. ("Uchikubo") and further in view of U.S. Patent No. 6,915,266 to Saeed et al. ("Saeed"); has rejected claims 2 and 9 under 35 U.S.C. § 103(a) as unpatentable over Knight in view of Uchikubo, further in view of Saeed and further in view of U.S. Patent Publication No. 2004/0078238 to Thomas et al. ("Thomas"); has rejected claims 7 and 31 under 35 U.S.C. § 103(a) as unpatentable over Knight in view of Uchikubo, further in view of Saeed and further in

view of U.S. Patent Publication No. 2003/0208378 to Thangaraj et al. ("Thangaraj"); and has rejected claim 22 under 35 U.S.C. § 103(a) as unpatentable over Knight in view of Uchikubo, further in view of Saeed and further in view of U.S. Patent No. 5,111,395 to Smith et al. ("Smith").

Claim Amendments

Each of the remaining independent claims in the present case has been amended to more clearly claim the exchange of data among the separate communicating parts of the invention. Specifically, independent claims 1 and 24 now require that (1) the identity of the proposed clinical trial candidate be forwarded to the candidate contact *from the data exchange server*, while (2) information about the clinical trial be forwarded to the candidate contact *from the clinical trial candidate identification service*. Thus, each of those claims now requires that those two pieces of information be forwarded to the candidate contact *from different parts* of the inventive system. Those two pieces of information are therefore not united until they reach the trusted candidate contact. Support for those amendments can be found at least in Fig. 4 and paragraphs [0052] - [0054].

In addition, the remaining independent claims 13 and 23, together with their associated dependent claims, have been canceled; independent claims 1 and 24 have been amended to remove amendments related to encryption that were added in a previous response, and claims 36 and 37 have been added to re-present claims related to encryption that were canceled in a previous response.

Discussion

Each of the independent claims in the case requires that the clinical data source be a database containing transactions between healthcare providers and payers. Such a database provides unique advantages for clinical trial selection because of the data's high reliability. Previous clinical trial candidate selection systems, however, did not use such data because strict anonymity requirements made it impractical. The claimed method permits the use of such a database by maintaining the privacy of candidates in an automated environment suitable for receiving such data.

To maintain a candidate's privacy, the system and method of the present invention keeps the identity of the patient separate from the patient's medical history. That is done by a data exchange service (DES) by replacing the patient's identity with a secure patient code, as claimed in each of the independent claims. The patient's medical history, together with the secure patient code, are then forwarded to a clinical trial candidate identification service (CTCIS)

Once a patient is selected by the CTCIS as a candidate for a particular trial, that patient must be contacted through a trusted candidate contact such as the patient's medical doctor. Because the patient's identity is given to the candidate contact in the clear, there is an additional danger in that step that the patient's selection to participate in a particular medical trial may be made public. The combination of those two pieces of information (candidate identity plus medical trial information) could reveal sensitive medical information about the patient.

The system and method of the present invention address that problem by forwarding those two pieces of information separately from two different sources to the candidate contact. For example, independent method claim 1 now includes the additional step of:

forwarding the identity of the proposed clinical trial candidate from the data exchange service to a candidate contact; and

forwarding from the clinical trial candidate identification service to the candidate contact, descriptive information about the clinical trial.

Similarly, independent system claim 24 requires:

[a CTCIS for] forwarding the secure patient code of the identified patient record to the data exchange service, and forwarding information about the clinical trial to a candidate contact;

the data exchange service being further for determining an identity of a patient from the secure patient code of the identified patient record, and forwarding the identity of the patient to the candidate contact.

Each of the independent claims therefore now requires that the candidate identity and medical trial information be forwarded to the candidate contact from separate entities.

No such system is taught or suggested by any of the cited art. Knight teaches a single server that gathers medical information and communicates with a potential candidate in a Web session (Knight at [0114]). All information is received by the candidate from a single server. The communications in Knight therefore contain potentially sensitive combinations of information, such as a patient address and trial information. Instead of separating sensitive information as is done in the technique of the present application, Knight encrypts the Web session to address that problem (Knight at [0114]).

Knight therefore does not teach or suggest a method and system wherein an identity of a patient and information about the clinical trial are forwarded separately by different entities to a candidate contact.

Uchikubo teaches sending data between two entities. Specifically, medical images and patient identification information are sent from an operating device portion located in a surgical operating room to a remote supporting device located in a remote control room. A combination of those two pieces of information could compromise the privacy of the patient. Unlike the separate forwarding performed in the present invention, Uchikubo transmits both pieces of information from a single server, making it possible that the combined information could be compromised. To address that problem, Uchikubo encrypts the patient identification information (Uchikubo at [0010], [0038], [0079]).

Saeed teaches a method of managing medical practice management agents. Saeed does not teach the forwarding of separate pieces of information by separate entities to a patient or clinical trial candidate.

Thomas teaches a method and system for anonymizing medical data for the research community while preserving the ability to trace that data back to particular patients (Thomas at [0002]-[0006]). That is done by substituting anonymous identifiers for patient identifiers in the data, and maintaining a database correlating those anonymous identifiers with the original patients (Thomas at [0014]-[0015]). Thomas does not address the problem of clinical trial candidate selection, and does not teach forwarding clinical trial information from one source while forwarding a patient identity from another source. Instead, Thomas teaches that a primary care physician may trace patient results (not information about a selected clinical trial) back to a particular patient by accessing the correlation database (Thomas at [0017]). Both pieces of

information are received by physicians in the primary care network 20 from the anonymizing network system 29 (Thomas, FIG. 1); Thomas therefore does not teach the claimed method wherein two separate entities forward to a candidate contact the two separate pieces of information.

The combination of at least (1) utilizing a database containing transactions between health care providers and payers, while (2) maintaining separation of patient identification and clinical trial information until in the hands of the patient contact, results in a system that utilizes highly reliable data without compromising privacy. The claimed technique protects the privacy of potential candidates in an automated environment and thereby permits the use of a transactional database, which, to the inventors' knowledge, has never before been used for medical trial candidate identification and selection.

Applicants therefore assert that each of the currently presented claims is patentable for those reasons.

Conclusion

Applicants therefore respectfully assert that claims 1-3, 6, 7, 9-11, 24-27, 30, 31 and 33-37 and are in condition for allowance, and earnestly request that the Examiner issue a Notice of Allowance.

Should the Examiner have any questions regarding the present case, the Examiner should not hesitate in contacting the undersigned at the number provided below.

Respectfully,

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